



Tennessee Immunization Program

Vaccines for Children Program Handbook

2016

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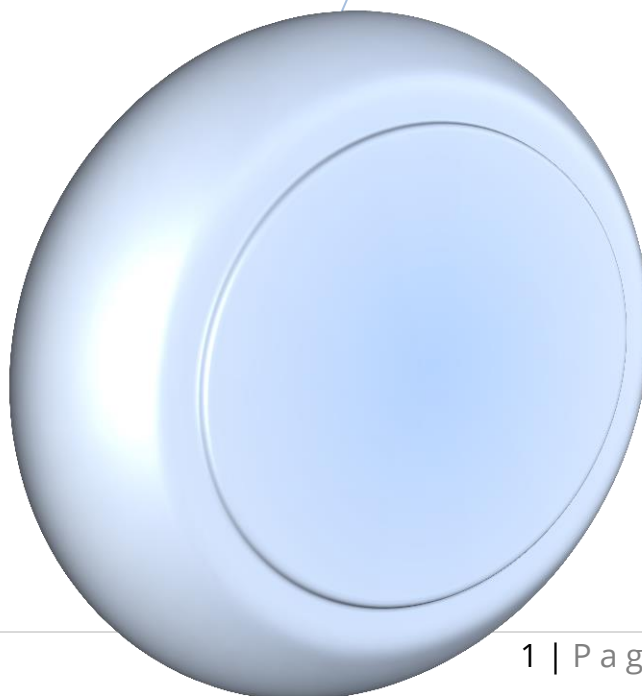


Table of Contents

Introduction	4
Acronyms	5
TIP Contact Information	6
1. Enrollment	8
1.1 Who May Enroll	8
1.2 Initial Enrollment & Annual Enrollment Process	8
1.3 Provider Identification Number	10
1.4 Provider Practice Profile	10
1.5 Changes in Staff/Facility Status	11
1.6 Inactivation	11
1.7 Fee Policies for Vaccines	12
1.8 Fraud and Abuse	12
2. Vaccine Eligibility and Administration Documentation	13
2.1 VFC Eligibility Categories	13
2.2 Documentation	15
2.3 Vaccine Administration Documentation	16
2.4 Vaccine Information Statement (VIS), Vaccine Adverse Events	16
3. Vaccine Ordering and Accountability	16
3.1 Ordering Vaccine	16
3.2 Vaccine Inventory	17
3.3 Receiving Vaccine	17
3.4 Vaccine Returns	18
3.5 Borrowing of Vaccine	18
3.6 Vaccine Transfers	18
4. Vaccine Storage and Handling	19
4.1 Storage and Handling	19

4.2	Vaccine Coordinator (aka Primary VFC Contact)	19
4.3	Vaccine Storage Units	20
4.4	Thermometers	21
4.5	Certificate of Calibration Testing	22
4.6	Temperature Probe Placement.....	24
4.7	Temperature Monitoring	24
4.8	What is a Temperature Excursion (TE)?.....	24
4.9	Reporting a Temperature Excursion	25
5.	Vaccine Management	28
5.1	Routine Vaccine Storage and Handling Plan.....	28
5.2	Emergency Vaccine Storage and Handling Plan.....	29
5.3	Vaccine Storage	29
6.	Quality Assurance Visits.....	30
6.1	Provider Enrollment Visit	31
6.2	VFC Compliance Site-Visit	31
6.3	Unannounced Storage and Handling Site-Visit	31
6.4	Annual Education Requirement.....	31
6.5	VFC Contact	31
6.6	Assessment, Feedback, Incentives, eXchange (AFIX) Visit	32
7.	Mobile Immunization Clinic	32
	Appendix A: Resources	36
	Appendix B: Flowchart for Initial VFC Enrollment.....	37
	Appendix C: Examples of Insured Exceptions.....	38
	Appendix D: Patient Eligibility Screening Record	39
	Appendix E: Guide to Selecting a Digital Data Logger	40
	Appendix F: Packing Vaccines for Emergency Transport	42

Introduction

The Tennessee Immunization Program (TIP) is in the Tennessee Department of Health (TDH), under the Communicable and Environmental Disease Services and Emergency Preparedness (CEDEP) division.

Our Mission:

To protect people of all ages in Tennessee from vaccine-preventable diseases.

Our Vision:

A Tennessee free of vaccine-preventable diseases.

Core Values:

- Credibility – Honest and accurate in all we do.
- Innovation – Creative and responsive on changing times.
- Accountability – Serve customers with integrity and compassion.

The Vaccines for Children Program (VFC) is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated due to inability to pay. TIP provides federally purchased vaccine to eligible health care providers enrolled in the in the VFC Program. Children who are eligible for VFC vaccines are entitled to receive pediatric vaccines that are routinely or permissively recommended by the Advisory Committee on Immunization Practices (ACIP), as published in the CDC's Recommended Immunization Schedules for Persons aged 0 through 18 Years (<https://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html>).

VFC Program Benefits:

- Provides cost-savings to states and territories through bulk purchase of vaccine at lower prices using federal contracts, and eliminates state-to-state differences in price.
- Reduces referrals of children from private providers to local health departments (LHDs) for vaccination.
- Saves VFC-enrolled providers out-of-pocket expenses for vaccine.
- Eliminates vaccine cost as a barrier to immunizing eligible children.

Acronyms

ACIP	Advisory Committee on Immunization Practices
AFIX	Assessment, Feedback, Incentives, eXchange
CDC	Centers for Disease Control and Prevention
DDL	Continuous temperature monitoring device, or “Digital data logger”
FQHC	Federally Qualified Health Center
EHR	Electronic Health Record
HL7	Health-Level 7 (the standards for electronic transmission of health data)
HRSA	Health Resources and Services Administration
LHD	Local Health Department
PIN	Provider Identification Number
RHC	Rural Health Center
RIR	Regional Immunization Representative
TE	Temperature Excursion
TennIIS	Tennessee Immunization Information System
TIP	Tennessee Immunization Program
U.S. DHHS	United States Department of Health and Human Services
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children Program
VIS	Vaccine Information Statement
VOMS	Vaccine Ordering and Management System

TIP Contact Information

VFC Enrollment and Operations – General VFC enrollment questions or to update designated Primary and/or Back-up VFC Contacts.

Phone:	(615) 532-8501
Email:	VFC.Enrollment@tn.gov
Available:	Monday thru Friday 8:00am to 4:30pm CDT

VFC Quality Assurance – Information about proper vaccine storage and handling, temperature excursions and program compliance questions or concerns.

Phone:	(800) 404-3006
Fax:	(615) 401-6829
Email:	VFC.Help@tn.gov
Available:	Monday thru Friday 8:00am to 4:30pm CDT

VOMS Vaccine Operations – Information regarding vaccine management that includes ordering, reconciliation, returns, and VOMS training and user permissions

Phone:	Public Health Departments - (615) 532-8511 All other VFC Providers - (615) 253-6915
Email:	TennIIS.VOMS@tn.gov
Available:	Monday thru Friday 8:00am to 4:30pm CDT

TennIIS Help Desk – General TennIIS assistance

Phone:	(844) 206-9927
Email:	TennIIS.Help@tn.gov
Available:	Monday thru Friday 7:00am to 6:00pm CDT

TennIIS Facility Registrations and User Updates – Information on how to register a facility in TennIIS, to add or inactivate users, or to apply the standard user permissions

Phone:	(615) 532-6151
Email:	TennIIS.Registration@tn.gov
Available:	Monday thru Friday 8:00am to 4:30pm CDT
Website:	https://www.tennesseeiis.gov

TennIIS Training – To sign-up for a live TennIIS webinar training or to inquire about on-site training

Phone:	(615) 532-6608
Email:	TennIIS.Training@tn.gov
Available:	Monday thru Friday 8:00am to 4:30pm CDT

Electronic Data Trading and Meaningful Use – Information on how to exchange data electronically with your Electronic Health Record (EHR) with TennIIS

Phone:	(615) 253-1360
Email:	TennIIS.MU@tn.gov
Available:	Monday thru Friday 7:30am to 4:00pm CDT

The documents and forms referenced in this document can be found on the TDH TIP website at: <http://www.tn.gov/health/article/vfc-provider-guidance>.

1. Enrollment

1.1 Who May Enroll

To participate in the Tennessee VFC Program, a healthcare provider must have an active, unencumbered medical or advanced nursing practice license in the state of Tennessee. In addition to providing practice information, Advance Nurse Practitioners and Physician Assistants must submit their supervising physician's name and medical license number. This information is submitted on the VFC Provider Agreement Enrollment form.

Providers enrolling in the VFC Program agree to all conditions contained in the Provider Agreement and this handbook.

1.2 Initial Enrollment & Annual Enrollment Process

Providers are required to renew enrollment with the VFC Program annually. If you are enrolling in the VFC Program for the first time you will first need to register for a full-access TennIIS user account (if not already a user) and request a Starter Kit from the VFC Program. Once inside TennIIS, refer to the Enrollment Walkthrough Guide that can be found in TennIIS under the Document Center for detailed instructions on completing the enrollment process.

Initial Enrollment Process (Appendix B):

1. VFC enrollment requires an active TennIIS user account. Those without an account may register as a TennIIS user at:
<https://tennesseeiis.gov/tnsiis/registration/register.do2?actionType=Enrollment>.
2. Once you have received email confirmation that your organization has been set up with TennIIS account, you may send an email to the VFC Program at VFC.Enrollment@tn.gov with your organization name and your intent to enroll in the VFC Program.
3. Complete the below training modules required of all new VFC clinics:
 - TennIIS training – information is available on the TennIIS homepage under the TennIIS Training tab. All staff expected to use TennIIS should go through training.

- Vaccine Ordering Management Training (VOMS) – training video about how to order VFC vaccine and manage your VFC vaccine inventory is available on the TennIIS homepage under the TennIIS Training tab. This should be viewed by at least 2 people responsible for VFC vaccine ordering (likely the Primary and Back-up VFC Contacts).
 - The Primary and Back-up VFC Contact need to complete two of the CDC’s online “You Call the Shots” modules: [Vaccine Storage and Handling](#) and [Vaccines for Children](#).
4. Complete the [Routine and Emergency Vaccine Management Tool](#).
 5. Complete the Provider Agreement in TennIIS.
 6. **Scan/Email the below required documents to VFC.Enrollment@tn.gov:**
 - Certificates of completion for the CDC You Call the Shots trainings
 - Provider Agreement Signature Page
 - Routine and Emergency Vaccine Management Plan
 - If your facility is a Federally Qualified Health Center (FQHC) or Rural Health Center (RHC), email the Notice of Award from the U.S Department of Health and Human Services (DHHS) Health Resources and Services Administration (HRSA) that validates your designation.
 7. The Regional Immunization Representative (RIR) will contact you to schedule an enrollment site-visit.
 8. Email five days of temperature readings for each vaccine storage unit to the TIP Quality Assurance team at VFC.Help@TN.gov.
 9. Place first VFC vaccine order in TennIIS.

Annual Renewal of Enrollment Process:

1. The VFC Program will email an enrollment reminder to the Primary and Back-up VFC Contact 60 days before your current agreement expires. If a Provider Agreement expires without renewal, you will not be able to place a new vaccine order until a new Provider Agreement is approved. The VFC Program may require you to go through the full initial enrollment process if enough time has elapsed between enrollments.
2. Primary and Back-up VFC Contacts both need to complete one of the below trainings within the current enrollment period:
 - Participate in a VFC Compliance Site Visit

- Complete two of the CDC’s online “You Call the Shots” modules: [Vaccine Storage and Handling](#) and [Vaccines for Children](#).
3. Review, update as needed, and sign the Routine and Emergency Vaccine Management Plan.
 4. Login to TennIIS to add and complete a new Provider Agreement for your facility. This feature is under the Orders/Transfers tab.
 5. Fax to (615) 401-6831 or email VFC.Enrollment@tn.gov the following:
 - Required Training Records (e.g., certificate from each of the CDC You Call the Shots modules, or verification of participation in a compliance site visit)
 - Provider Agreement Signature Page
 - Routine and Emergency Vaccine Management Plan
 6. TennIIS will email the certifying provider (provider that signed Provider Agreement) and Primary VFC Contact during enrollment concerning any status changes of the online agreement.

VFC Record Retention: Providers are required to maintain all records related to the VFC Program for a minimum of three years and make these records available upon request for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.

1.3 Provider Identification Number

The VFC Program will issue each facility a unique six-digit Provider Identification Number (PIN). Use this number in **ALL** email, fax, mail and phone interactions with the VFC Program. Referencing the PIN number in the subject line of any correspondence with TIP will expedite communication.

1.4 Provider Practice Profile

The Provider Practice Profile is a section within the Provider Agreement in TennIIS. This section of the agreement defines the number of children who received vaccinations for the full prior year at each facility. The Provider Practice Profile identifies eligibility status by age group. If you are completing an annual renewal of enrollment, the Provider Practice Profile will auto-populate with administration data for the prior year. Review carefully and update the numbers accordingly. It is

essential to be accurate when describing your patient population in the Provider Practice Profile. Billing staff may be able to help you respond to this section of the Provider Agreement if you are using patient records to help determine your Provider Practice Profile. TIP uses the information in the profiles to determine the amount of vaccine each provider will need in the year ahead.

1.5 Changes in Staff/Facility Status

Providers are required to contact the VFC Program within **ten days** of any change to the following:

1. Certifying provider (provider that signed Provider Agreement)
2. Primary VFC Contact
3. Back-up VFC Contact
4. Listed medical providers
5. Mailing/shipping address
6. Vaccine delivery hours
7. Facility status

Any new certifying provider, Primary VFC Contact, and/or Back-up VFC Contact, at a current VFC practice must complete either a VFC compliance site visit or the 2 online CDC You Call the Shots required modules (Vaccines for Children and Vaccine Storage and Handling) within 30 days of notifying TIP of their new role.

1.6 Inactivation

Enrolled facilities may be inactivated due to:

Facility Request:	In the event of a facility closure or withdrawal from VFC, immediately notify TIP in writing (email or letter).
Failure to comply with VFC requirements:	During enrollment to receive VFC vaccines, providers agree to adhere to federal and state VFC requirements. If these requirements are not being followed, TIP may investigate and, if necessary, inactivate the provider.
Failure to complete annual enrollment:	If current VFC participants fail to renew enrollment, TIP will inactivate the provider.

Please Note: TIP will contact inactivated providers with instructions on the transfer or return process for all VFC vaccines on hand. The provider is responsible for maintaining proper storage and temperature monitoring until vaccine is retrieved.

1.7 Fee Policies for Vaccines

Provider receiving federal vaccine must comply with the following fee policies:

1. Immunize VFC-eligible children at no cost to the patient or health plan (i.e., payer) for the cost of a vaccine received through the VFC Program.
2. A provider must not charge a vaccine administration fee to a non-TennCare VFC-eligible child that exceeds the administration fee cap of **\$20** per vaccine dose. For TennCare VFC-eligible children, accept the reimbursement for immunization administration set by the contracted TennCare health plans.
3. A provider must not deny administration of VFC vaccine to an established VFC-eligible patient whose parent/guardian/individual of record is unable to pay the administration fee.

1.8 Fraud and Abuse

Federal fraud and abuse laws apply to the VFC Program. A working understanding of what constitutes fraud and abuse is critical for all persons involved with the VFC Program. The following definitions are consistent with “fraud” and “abuse” as defined in the Medicaid regulations at 42 CFR § 455.2:

1. **Fraud:** An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.
2. **Abuse:** Provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for healthcare. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.

Fraud or abuse can occur in many ways. Some types of fraud and abuse are easier for the VFC Program to prevent or detect than others. Some examples of potential fraud and abuse that VFC staff might encounter are:

1. Providing VFC vaccine to non-VFC-eligible children
2. Selling or otherwise misdirecting VFC vaccine
3. Billing a patient or third party for VFC-funded vaccine
4. Charging more than the established maximum regional charge for administration of a VFC-funded vaccine to a VFC-eligible child
5. Denying VFC-eligible children VFC-funded vaccine because of an inability to pay for the administration fee
6. Failing to implement provider enrollment requirements of the VFC Program
7. Failing to screen for and document eligibility status at every visit
8. Failing to maintain VFC records and comply with other requirements of the VFC Program
9. Failing to fully account for VFC-funded vaccine
10. Failing to properly store and handle VFC vaccine
11. Ordering VFC vaccine in quantities or patterns that exceed the provider's profile or otherwise over-ordering VFC doses of vaccine
12. Negligent waste of VFC vaccine

2. Vaccine Eligibility and Administration Documentation

In order for children to receive vaccines through the VFC Program, eligibility screening and documentation must take place at **each** immunization visit, within 24 hours, prior to vaccination. The only factors considered when screening for VFC eligibility are age and whether the child meets the definition of at least one of the VFC criteria described below.

2.1 VFC Eligibility Categories

Children through 18 years of age (under 19) who meet at least one of the following criteria are eligible to receive VFC vaccine:

1. **Medicaid-eligible:** A child who is eligible for the Medicaid program. (For the purposes of the VFC Program, the terms “Medicaid-eligible” and “Medicaid-enrolled” are used interchangeably and refer to children who have health insurance covered by the TennCare program.)
2. **Uninsured:** A child who has no health insurance coverage.
3. **American Indian or Alaska Native (AI/AN):** As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603).
4. **Underinsured:** Underinsurance, limited coverage, and “caps” should be rare instances with the implementation of the Affordable Care Act (ACA).
 - A child who has health insurance, but the coverage does not include vaccines, or
 - A child whose insurance does not cover all Advisory Committee on Immunization Practices (ACIP) - recommended vaccines. The child would be eligible to receive from VFC only those vaccines not covered by the insurance.
 - A child whose insurance caps its payment for vaccine coverage. The child is eligible to receive VFC vaccine after the insurance cap has been reached. If the cap is expected to be reached as a result of the cost of all of the services provided at the visit, VFC vaccine may be used.

Please note: Underinsured children are eligible to receive VFC vaccine only through a FQHC, RHC, or LHD.

Insurance Coverage: Children whose health insurance covers vaccinations as a benefit **are not eligible** for VFC vaccines. ***This applies even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan’s deductible has not been met.***

CoverKids: This state child health insurance plan is not part of Medicaid; children with CoverKids are ineligible for VFC vaccine.

Insured Exceptions include: (Appendix C)

<p>American Indian/Alaska Native with health insurance that covers immunizations.</p>	<p>AI/AN children are always VFC-eligible. For AI/AN children that have <u>full immunization benefits</u> through a primary private insurer, the decision to participate in the VFC Program should be made based on what is most cost beneficial to the child and family.</p>
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<p>Insured, plus Medicaid as secondary insurance.</p>	<p>A child may have private health insurance and Medicaid as secondary insurance. This child is VFC-eligible as long as he is enrolled in Medicaid. However, the parent is not <i>required</i> to participate in the VFC Program. There are two options:</p> <ol style="list-style-type: none"> 1. Administer VFC vaccine and bill Medicaid for the administration fee, or 2. Administer private stock vaccine and bill primary insurance for both the cost of vaccine and the administration fee.
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2.2 Documentation

VFC eligibility screening and documentation of eligibility status must take place with each immunization visit, up to 24 hours in advance, to ensure the child's eligibility status has not changed. A record of all children 18 years of age or younger who receive immunizations must be kept in the health care provider's office for three years. While verification of responses is not required, it is necessary to retain a paper or electronic record for each child receiving vaccine. If the eligibility cannot be documented in the EHR, eligibility may be recorded on the [Patient Eligibility Screening Record](#), (Appendix D) and scanned into the EHR or maintained in the paper chart. The record may be completed by the parent, guardian, individual of record, or by the health care provider. Eligibility status documentation (paper or electronic) must include each of the following:

1. Child's first and last name and middle initial
2. Child's date of birth
3. Parent/Guardian/Individual of Record's first and last name and middle initial;
4. Primary provider's name
5. Date of each immunization visit
6. One of the following eligibility statuses:
 - Medicaid eligible/enrolled
 - Uninsured
 - American Indian/Alaska Native
 - Underinsured (served at FQHC, RHC, or LHD)
 - Insured (Private stock vaccine)

2.3 Vaccine Administration Documentation

In accordance with Federal law 42 US Code 300aa-25, all VFC providers must maintain immunization records that include ALL of the following elements:

1. Name of vaccine administered
2. Date vaccine was administered
3. Date VIS was given
4. Publication date of VIS
5. Name of vaccine manufacturer
6. Lot number
7. Name and title of person who administer the vaccine
8. Address of clinic where vaccine was administered

Beginning January 1, 2017, all VFC providers will be required to record in TennIIS every vaccine administered to all patients <19 years of age, regardless of VFC status.

2.4 Vaccine Information Statement (VIS), Vaccine Adverse Events

All vaccine providers, public or private, are required by the National Vaccine Childhood Injury Act (NCVIA) to give the appropriate VIS to the patient (or parent or legal representative). The appropriate VIS must be given **prior** to the vaccination, and must be given prior to **each dose** of a multi-dose series. It must be given **regardless of the age** of the recipient. Providers must maintain records in accordance with the NCVIA, which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov. Deaths or severe reactions possibly associated with immunization also should be reported to TIP by phone.

3. Vaccine Ordering and Accountability

3.1 Ordering Vaccine

All VFC vaccine requests must be placed through TennIIS's Vaccine Ordering and Management System (VOMS). Training materials consisting of short videos and/or

PDF instructions on creating, submitting and receiving vaccine orders are available on the [TennIIS homepage](#) under the TennIIS Training tab. There is a quick reference guide [Create, Submit and Receive Vaccine Orders](#) available to assist in the process.

3.2 Vaccine Inventory

VFC providers are responsible for proper maintenance of their vaccine inventory. Provider sites must reconcile their VFC vaccine inventory every 30 days using VOMS. Reconciliation is an accounting of vaccine doses administered, doses wasted, doses expired, lost (unaccounted for) and the vaccine doses currently in your inventory. This degree of vaccine dose-level accountability is required by CDC.

1. Providers are required to reconcile their inventory every 30 days; even if a vaccine order is not placed.
2. Vaccine requests will not be processed unless reconciliation reports are up-to-date in TennIIS.
3. Review the TennIIS Quick Reference Guide Inventory Reconciliation.

3.3 Receiving Vaccine

Providers must have procedures in place for immediate receipt and storage of vaccine due to its temperature sensitivity. All staff must be trained to recognize a vaccine shipment and the procedures to follow once received. The following steps should happen upon receipt of a vaccine shipment:

1. Open vaccine packages immediately
2. Inspect the vaccine and packaging for damage
3. Compare the vaccine received with the vaccine products that appear on the packing list
4. Immediately store at appropriate temperatures
5. Check the temperature monitor readings (if available)
6. (Frozen vaccine only) Verify length of time the vaccine was in transit. Check the shipper insert supplied in the box. This insert will let you know the acceptable transit time based on the shipment date on their packing list.
7. If the vaccine shipment is compromised or there is a problem with the temperature monitors, contact the TIP VFC Program immediately, **within 2 hours**, at 615-532-8509 or 800-404-3006. It is critical that TIP contact

McKesson the same day the vaccine arrived at your site, otherwise the shipper may not be held accountable for replacing a damaged shipment.

8. Login to TennIIS/VOMS and electronically indicate receipt of the order in the Orders/Transfer page.
9. REMEMBER: If there are any discrepancies in expected/received inventory or damage to the vaccine shipment, reporting this to TIP is required within two hours of receiving the shipment.

3.4 Vaccine Returns

Report all VFC vaccine that has expired or has been spoiled/wasted to the VFC Program so it can be returned to McKesson. Inventory will need to be reconciled in TennIIS in order to receive a shipping label to send vaccine to McKesson. See the quick reference guide for [Returning Vaccines](#) available on the TennIIS homepage.

3.5 Borrowing of Vaccine

VFC-enrolled providers are expected to maintain adequate inventories of vaccine to administer to their privately insured and VFC-eligible children. Borrowing of vaccine between VFC and private vaccine inventories is not allowed unless specifically authorized in advance by the TIP VFC Program under extraordinary circumstances. For approval, contact the TIP VFC Program at 615-532-8509 or 800-404-3006.

If approved, borrowing must be documented “dose-by-dose” for each patient on the [Vaccine Borrowing Form](#).

3.6 Vaccine Transfers

It is important to report to TIP any VFC vaccine with short expiration dates (vaccines expiring within three months) unlikely to be used before they expire. This allows the VFC Program the opportunity to have vaccines transferred to another VFC site. Contact your RIR to determine if there are other VFC providers in your area that could use the expiring vaccine. After notifying TIP and your RIR, another option is to use the Vaccine Advertisement function in TennIIS to find providers in your area that can use the vaccine by the expiration; see the quick reference guide for the [Vaccine Advertisement Screen](#).

4. Vaccine Storage and Handling

4.1 Storage and Handling

Just 10 doses of each routinely recommended child/adolescent vaccine is valued at over \$10,000; most practices have far larger inventories. Vaccines must be stored appropriately in order to work as designed. A temperature controlled environment used to maintain and transport vaccines in optimal condition is called the vaccine cold chain. An effective vaccine cold chain relies on three main elements:

1. Effectively trained personnel
2. Reliable storage and temperature monitoring equipment
3. Accurate vaccine inventory management

Vaccine storage and handling practices are only as effective and successful as the staff that implements them. A well-trained staff, familiar with key storage and handling principles, is critical to safeguarding your vaccine supply and the safety of your patients.

4.2 Vaccine Coordinator (aka Primary VFC Contact)

Each VFC site is required to designate a primary VFC Contact for the facility. This person will be responsible for ensuring all vaccines are stored and handled correctly. Each site also is required to designate a second staff member to serve as back-up in the absence of the primary VFC contact. The certifying provider on the Provider Agreement is not able to serve as the Primary or Back-up VFC Contact. For providers that have multiple sites, a VFC Contact may not be assigned to multiple sites; a primary and back-up VFC Contact must be assigned and on-site at each location. Both VFC Contacts should be fully trained in routine and emergency policies and procedures.

VFC Contact responsibilities include:

1. Ordering vaccines
2. Overseeing proper receipt and storage of vaccine deliveries
3. Documenting vaccine inventory information
4. Organizing vaccines within storage units
5. Setting up temperature monitoring devices

6. Reading and recording storage unit temperatures a minimum of 2 times each workday
7. Reading and recording minimum/maximum temperatures from a digital data logger one time each workday, preferably each morning
8. Reviewing and analyzing temperature data at least weekly to detect any concerning temperature trends
9. Rotating stock at least weekly so vaccines with the earliest expiration dates are used first
10. Removing expired vaccine from storage units
11. Responding to out-of-range temperatures (temperature excursion, “TE”)
12. Maintaining all documentation, such as inventory and temperature logs
13. Ensuring staff is properly trained
14. Monitoring operation of storage equipment and systems
15. Overseeing proper vaccine transport (if necessary)
16. Overseeing emergency preparations

4.3 Vaccine Storage Units

Refrigerators and freezers typically used for vaccine storage are available in different grades (household and purpose-built) and types (stand-alone and combination refrigerator/freezer). Purpose-built units are sometimes referred to as “pharmaceutical grade” and are designed specifically for storage of biologics. It is important that the storage unit has enough space to store the largest inventory you might have at the busiest point in the year (e.g., flu season) without crowding. The following storage units are acceptable for storing VFC vaccine:

1. A purpose-built unit for vaccine storage designed to either refrigerate or freeze (can be compact, under-the counter-style or large units).
2. If a purpose-built unit is not available, use a stand-alone household refrigerator and freezer unit (frost-free).
3. If you *must* use a household-grade combination refrigerator/freezer unit, only the refrigerator compartment may be used for storing vaccines. Such units are *not* recommended because of the increased risk of vaccine damage. These units have cold spots and temperature fluctuations, and air circulating from the freezer could expose refrigerated vaccines to freezing

temperatures. A separate stand-alone freezer (frost-free) is required to store frozen vaccines.*

***Policy Note:** As of August 1, 2016, all **newly enrolling VFC providers** will be required to have a stand-alone refrigerator and freezer storage unit or a specialized combination unit purpose-built for safe vaccine storage. Beginning January 1, 2018, current VFC providers will no longer be able to use a household-grade combination refrigerator/freezer unit.

Dormitory or bar-style refrigerators are not permitted for **ANY** vaccine storage. A dormitory or bar-style refrigerator is defined as a small combination refrigerator/freezer unit that is outfitted with one external door and has an evaporator plate (cooling coil) which is usually located inside the “freezer” within the refrigerator. Such refrigerators place vaccine at a high risk of freezing.

4.4 Thermometers

VFC providers are required to have a digital data logger (DDL) with a physically or electronically buffered probe or a digital minimum/maximum thermometer with a current and valid certificate of calibration testing in each vaccine storage unit. CDC recommends the use of a DDL with a buffered probe to reflect the slower temperature changes of liquid vaccines, rather than the brief and more variable fluctuations of air temperatures in the unit that do not change the vaccine temperatures. DDLs that measure air temperature may be used but must be set to the same alarm parameters as buffered probe DDLs. DDLs provide more accurate and comprehensive documentation of TEs to which vaccines may be exposed. The DDL should include the following features:

1. A detachable, buffered probe (or digitally buffered device that mimics a buffered probe)
2. Alarm (audible or visual) for out-of-range temperatures
3. Current, minimum, and maximum temperatures
4. An active display outside the unit so there is no need to open the unit door while conducting routine checks of the storage temperatures
5. Low battery indicator
6. Accuracy of +/- 1°F (0.5°C)
7. Memory storage of at least 4,000 readings

8. User programmable logging interval (or reading rate)
9. Data is easily downloadable for review

Note Policy Change: The few current VFC providers lacking a DDL may still use a digital min/max thermometer with a current certificate of calibration testing. If purchasing a new thermometer, please purchase a DDL that complies with the above guidelines. (Appendix E). As of August 1, 2016, **all newly enrolled VFC providers** will be required to use a DDL in all vaccine storage units. Beginning January 1, 2018, **all** VFC providers will be required to use DDLs.

The following VFC providers are currently required to use a DDL that complies with the above guidelines:

- **All LHDs**
- **Any provider that has a vaccine loss due to error or negligence**
- **Any provider office that is closed three or more days a week**
- **Any new VFC provider**

In addition, VFC providers **must have at least one backup thermometer** with a valid and current certificate of calibration readily available to ensure that temperature assessment and recordings can be performed twice a day. Backup thermometers must be readily available in case a DDL or thermometer in use is no longer working or calibration testing of the current DDL is required. CDC recommends that the backup thermometer be stored outside of the storage unit until needed to avoid vaccine space issues and differing temperature readings leading to potential confusion. The backup thermometer should have a different calibration retesting date than the primary so one may be used while the other is sent out for re-calibration at the same time. A min/max thermometer may be used as the back up to a DDL.

4.5 Certificate of Calibration Testing

Valid and current Certificates of Calibration Testing (or Reports of Calibration Testing) must be maintained on all thermometers used in vaccine storage units. Calibration testing and traceability must be performed by:

1. A laboratory accredited by an ILAC MRA signatory body (recommended by CDC). Certificate must include the following elements:
 - ILAC/MRA signatory body-accredited laboratory
 - a. Laboratory accreditation should be clearly identifiable (to search ILAC-accredited laboratories, see box below)
 - b. An ILAC MRA-accredited laboratory is the easiest way to identify that the instrument has been tested correctly according to international standards
 - c. The certificate may have an Accrediting Body Symbol, which is the logo, and a unique laboratory code or certificate number included on the certificate
 - Name of Device (optional)
 - Model Number
 - Serial Number
 - Date of Calibration Testing (report or issue date)
 - Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = $\pm 1^{\circ}\text{F}$ [0.5°C])
2. An entity that provides documentation demonstrating the calibration testing performed meets ISO/ IEC 17025 international standards for calibration testing and traceability. Certificate must include the following elements:
 - Name of Device (optional)
 - Model Number
 - Serial Number
 - Date of Calibration Testing (report or issue date)
 - Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = $\pm 1^{\circ}\text{F}$ [0.5°C])
 - Statement that calibration testing conforms to ISO 17025

If you are uncertain if the certificate you have conforms to these requirements, contact TIP or your RIR for help.

4.6 Temperature Probe Placement

The probe of your DDL should be placed in the central/middle area of the storage unit *with* the vaccines. Do not place the temperature probe in the doors, near or against the walls, close to vents, or on the floor of the vaccine storage unit.

4.7 Temperature Monitoring

Temperature monitoring is the primary responsibility of the Primary VFC Contact and/or Back-up Contact. It is required that temperatures are reviewed within each vaccine storage unit **twice a day** (morning and afternoon). This twice a day readings must be documented, as should any actions that are taken if the temperatures readings are out of acceptable range. Providers still using a digital minimum/maximum thermometer should document temperatures on the TIP [Temperature Logs](#). Facilities using DDLs should “read” the temperature per DDL manufacturer instructions and document this was done and that no TE alarms were present on the [Vaccine Storage Unit Digital Data Logger Sign-off Sheet](#) daily; the DDL report needs to be printed and reviewed for problems or trends *weekly*.

We recommend recording temperatures in Celsius. The refrigerator should maintain temperatures between 2°C and 8°C (36°F and 46°F). Set the temperature mid-range to achieve an average of 5°C (40°F). The freezer should maintain temperatures between -50°C and -15°C (-58°F and +5°F) at all times: aim for about -20°C (-4°F).

Please Note: Review the [Temperature Monitoring and Excursion Guide](#) on our website for more details on vaccine storage units and temperature monitoring.

4.8 What is a Temperature Excursion (TE)?

A TE occurs any time the temperature in a refrigerator unit is outside 2.0°C through 8.0°C (36° through 46°F) or the temperature in a freezer unit is above -15°C (5°F). TIP must be notified immediately during business hours or on the next business morning (8a-430p Central, week days), if any one of the below criteria are met:

1. Refrigerator temperature dipped below 2.0°C (36°F) for 15 consecutive minutes (or longer).
 - a. Freezing temperatures below 0°C (32°F) quickly damages vaccine. Quick action may save vaccine if temperature begins to get too cold.
2. Refrigerator above 8.0°C (46°F) for at least 60 consecutive minutes.

3. Freezer above -15°C (5°F) for *more* than 60 consecutive minutes.
 - b. Frost-free freezer defrost cycles may go above -15°C (5°F) for short periods. Vaccine stability data supports these types of excursions.
4. TE is part of a pattern of frequent excursions, regardless of duration.
5. You are concerned about TE even though it doesn't meet above criteria.

4.9 Reporting a Temperature Excursion

Report TE by calling the TIP QA Team at 800-404-3006 during business hours (Monday – Friday 8:00 am – 4:30 pm Central Time). If the call is not answered, call the CEDEP main desk at 615-741-7247 and ask them to locate someone in TIP.

1. If TE is still occurring (temperatures are currently out of range) take the following steps to restore proper storage conditions:
 - Attempt to return vaccine to proper storage conditions:
 - a. Check to see if the storage unit is unplugged
 - b. Check to see if the storage unit door is open and is sealed adequately
 - c. Check the thermostat setting
 - d. Check location of the probe; should be in the middle of the unit with the vaccine
 - e. Check the coils and vents for excess dust
 - Quarantine vaccine; label “Do Not Use until Notified by TIP”
 - a. Do not use any vaccine until approved by TIP
 - Immediately call the TIP QA team (if during business hours)
 - If instructed by TIP, or if after hours, follow your Emergency Storage and Handling Plan posted on or beside the storage unit. If storage unit cannot be used, transfer vaccine to the designated back up location.
 - Download temperature log from digital data logger or document current temperature reading on temperature log
 - Note how long the temperature was out of range
 - Note the minimum/ maximum temperatures
 - Fax data logger report or temperature log to 615-401-6829 or email to VFC.help@tn.gov
2. If temperature is currently “in range” complete the following steps:
 - Troubleshoot – can you identify why it went out of range?
 - Quarantine vaccine; label “Do Not Use until Notified by TIP”
 - Do not use any vaccine until approved by TIP
 - Immediately call the TIP QA team, if during business hours

- Download temperature log from digital data logger or document current temperature reading on temperature log
- Note how long the temperature was out of range
- Note the maximum and minimum temperatures
- Fax data logger report or temperature log to 615-401-6829 or email to VFC.help@tn.gov

3. Responding to TE **after Business Hours:**

- Attempt to return vaccine to proper storage conditions:
 - a. Check to see if the storage unit is unplugged
 - b. Check to see if the storage unit door is open and is sealed adequately
 - c. Check the thermostat setting
 - d. Check location of the probe; should be in the middle of the unit with the vaccine
 - e. Check the coils and vents for excess dust
- Quarantine vaccine; label "Do Not Use until Notified by TIP"
- Do not use any vaccine until approved by TIP
- Follow the Emergency Storage and Handling Plan posted on or near the unit.
 - a. If unit is not currently in range and vaccine cannot be reliably and promptly returned to proper temperatures, consider transferring vaccine to the designated back up location listed in your Emergency Storage and Handling Plan.
 - b. You may also temporarily store vaccine on site in a commercial transport box designed for vaccine transport to maintain temperatures between 2-8°C for the period of time specified by the manufacturer (e.g., a transport box with phase change material). A variety of options exist.
 - c. You may also use the emergency vaccine transport qualified pack-out (Appendix F) published by the CDC for temporary storage up to 8 hours. For packing instructions, see <http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf>
- **If experiencing a power outage, contact utility company. If restoration is expected within four hours, do not move vaccine.** Keep the door closed and monitor temperature. This brief TE may be less harmful than transporting vaccine. If power outage is going to last

more than four hours, follow your Emergency Storage and Handling Plan.

- ***As soon as TIP offices open*** (8AM Central Time), the next business day contact the QA Team to report TE.
 - If guidance is needed because vaccines need to be used *before* the next business day contact TIP at 615-741-7247 or 800-404-3006. You should still call TIP the next business morning.
 - a. Contact vaccine manufacturer's customer service lines directly to report the problem and obtain vaccine use guidance.
 - b. Alternatively, you may call 615-741-7247 and listen to the message to obtain the phone number of the on-call senior epidemiologist for CEDEP. This person will provide a basic consultation but will *not* provide advice on the viability of the vaccine. In emergencies where vaccine must be used before business hours (e.g., newborn nursery in a hospital), Dr. Kelly Moore may be contacted for further consultation or you may contact vaccine manufacturers directly.
4. If the TE is not reported immediately and there is vaccine loss as a result of the TE, the following actions will be taken:
- Provider will be placed on six month probation.
 - Provider will need to submit weekly temperature logs to their RIR for a specified period.
 - RIR will conduct an on-site education visit for the certifying provider, Primary and Back-up VFC Contact.
 - If using a combination R/F unit, the provider must purchase a stand-alone refrigerator; vaccine orders suspended until purchased.
 - If not using a DDL, provider must purchase and use a DDL.
 - Provider will receive two Unannounced Storage and Handling Visits.
 - At the successful conclusion of the six month probation the provider will resume routine monitoring.
 - a. If unable to maintain compliance with vaccine storage requirements, the site will be suspended from the VFC Program for six months. The RIR will pick up VFC vaccine. TIP will notify TennCare.

5. If TE is not reported immediately and there is **no** vaccine loss the following actions will be taken:
- Provider will be placed on six month probation.
 - Provider will need to submit weekly temperature logs to the RIR for a specified period.
 - RIR will conduct an on-site education visit for the certifying provider, Primary and Back-up VFC Contact.
 - If not already in use, provider must purchase a DDL and a stand-alone refrigerator.
 - At the successful conclusion of the six month probation the provider will resume routine monitoring.
 - If unable to maintain compliance with vaccine storage requirements, the site will be suspended from the VFC Program for six months. The RIR will pick up VFC vaccine. TIP will notify TennCare.

5. Vaccine Management

5.1 Routine Vaccine Storage and Handling Plan

VFC providers are required to develop, maintain and implement routine vaccine storage and handling plan. The plan must be updated annually and include a review date and the signature of the individual responsible for the content. The minimum required components of the plan include the following:

1. Name of the current primary VFC Contact and at least one back-up
2. General operations for proper vaccine storage and handling practices:
Temperature monitoring
 - Vaccine storage (e.g., equipment, placement)
 - Vaccine receiving procedures
3. Vaccine ordering procedures
4. Inventory control (e.g., stock rotation)
5. Vaccine expiration, spoilage, and wastage prevention (e.g., protocol for responding to and reporting vaccine loss)
6. Documentation of staff training on all plan elements
7. Recorded review date within the last 12 months

8. Signature of the individual responsible for the content

5.2 Emergency Vaccine Storage and Handling Plan

VFC providers are required to have an emergency vaccine storage and handling plan. The plan must include guidance on what to do in the event of:

1. Refrigerator or freezer malfunctions
2. Power failure to vaccine storage units
3. Natural disasters or other emergencies that might compromise vaccine storage conditions

The plan must include policies and protocols for maintaining the vaccine cold chain during transport to and while stored in emergency storage locations. We recommend your plans include the use of a commercial vaccine transport box qualified to maintain around 5°C for a specified number of hours or the use of the CDC emergency transport vaccine qualified pack-out,

<http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf>. The vaccine storage units and thermometers used at the emergency location site must be in compliance with VFC requirements. A Routine and Emergency Vaccine Management Plan template is available on our website at: <http://www.tn.gov/health/article/vfc-provider-guidance>.

5.3 Vaccine Storage

Placement and organization within the storage unit is vital to maintaining vaccine stability. The following are best practices for day-to-day vaccine management:

1. Store vaccines in their original packaging (including UV protective bags used by CDC's centralized distributor for repackaged vaccines only).
2. Store vaccines in the middle of the unit, with space between both the vaccines and the side/back of the unit.
3. Do not store vaccines in the doors, vegetable bins, or floor of the unit, or under or near cooling vents.
4. Do not store food or drink in vaccine storage units.
5. Place water bottles throughout refrigerator and freezer storage units and frozen coolant packs in order to:
 - Stabilize or extend temperatures during a power outage,
 - Dampen the effects of frequent opening/closing of door, and

- Serve as physical barriers preventing the placement of vaccines in areas of the unit that are at higher risk for TEs.
6. Rotate vaccine every week or when a new shipment comes in (whichever happens more frequently) so that newer vaccines are stored toward the back of the unit, while those soonest-to-expire are stored in the front. Immediately remove any expired vaccine from storage units. Bag and label all expired vaccine: "DO NOT USE".
 7. Open only one vial or box of a particular vaccine at a time to control vaccine use and allow easier inventory control. For multi-dose vials only, indicate on the label the date and time it was reconstituted or first opened.
 8. Store vaccine products that have similar packaging in different locations in the storage unit to avoid confusion and medication errors.
 9. Limit access to the vaccine supply to authorized personnel only.
 10. Install locks on refrigerators and, if possible, the electrical plug. Label the plugs "Do Not Disconnect."
 11. Safeguard public vaccines by providing facility security, such as temperature alarms and restricted access to vaccine storage and handling areas.
 12. In larger clinics, we recommend a source of back-up power (generator) and a security system to alert personnel in the event of a power outage.
 13. If applicable, test back-up generators quarterly and maintain back-up generators at least annually (check manufacturer specifications for test procedures and maintenance schedules).
 14. In regular clinics/practices, vaccines should be prepared immediately prior to administration. CDC and TIP strongly recommend NOT pre-drawing doses before they are needed.
 - Although not recommended, during mass vaccination clinics a provider may pre-draw up to 10 doses from a multi-dose vial and administer them. Manufacturer pre-filled syringes are also a good option in mass vaccination clinics.

6. Quality Assurance Visits

Federal and state requirements mandate that TIP conduct Quality Assurance (QA) visits, assessments and education with each enrolled VFC provider.

6.1 Provider Enrollment Visit

This visit is required for new enrolling providers or former VFC providers that have had a break between enrollments. The purpose of this visit is to provide education on VFC Program requirements and verify the facility has the appropriate resources to implement program requirements.

6.2 VFC Compliance Site-Visit

A compliance site visit consists of an examination of vaccine management and delivery practices to ensure compliance with federal and state VFC requirements. It involves administration of a questionnaire, evaluating compliance with requirements and providing education. During the visit, there will be a formal review of vaccine management practices as well as a review of patient records and other documentation to assure appropriate vaccine eligibility screening and administration documentation is occurring.

6.3 Unannounced Storage and Handling Site-Visit

The VFC Program requires unannounced storage and handling site visits be conducted to serve as “spot checks” on facility vaccine management practices.

Please Note: The RIR will meet with the provider and staff after the VFC Compliance and Unannounced Storage and Handling Visits is completed to review findings. Education will be provided for any noncompliance issues identified and a corrective action plan will be completed.

6.4 Annual Education Requirement

The primary and back-up VFC contacts are required to complete an annual educational session. The requirement can be met by participating in a VFC Compliance Site Visit or by completing the CDC’s online You Call the Shots modules “Vaccines for Children (VFC)” and “Vaccine Storage and Handling”.

6.5 VFC Contact

Any in-person, phone or written contact with a provider (not related to the most recent VFC Compliance or Unannounced Storage & Handling Visit). “VFC contacts” are directly related to communicating VFC Program requirements. Clarifying vaccine orders, formal educational opportunities (to meet the annual training requirement),

and follow-up for VFC Compliance or Unannounced Storage & Handling visits are not classified as VFC contacts.

A provider can request additional education and training, please contact your RIR.

6.6 Assessment, Feedback, Incentives, eXchange (AFIX) Visit

The CDC AFIX (Assessment, Feedback, Incentives, and eXchange) process is a research-supported continuous quality improvement and collaborative learning process between the VFC providers and the RIR. The goal of this process is to not only to increase immunization coverage but to sustain a high immunization coverage rate. This will ultimately prevent disease in the population. The AFIX process provides the VFC provider with opportunities to improve their quality of care by reviewing reports that identify missed opportunities, invalid doses, and patients who are not up-to-date with their immunizations.

In 2016, all AFIX visits will include a childhood and an adolescent assessment. The assessment is conducted on children ages 24 – 36 months and adolescents 13 – 18 years using immunization data found on active patients belonging to the practice as identified in TennIIS. Only immunizations recorded in TennIIS will be assessed, therefore it is very important for practices to add historical doses when updating patient records in order to have a complete record for an accurate AFIX assessment. The results of the assessment will be shared with the provider and staff during the AFIX site-visit. The RIR and the provider will work together to develop quality improvement strategies to improve their immunization services for children and adolescents.

7. Mobile Immunization Clinic

VFC providers may incorporate a mobile immunization clinic into their practice. A mobile immunization clinic allows providers to vaccinate more children in their community by offering VFC and private stock vaccines at non-traditional locations (e.g., schools and health fairs) while maintaining the convenience of a clinic setting and the vaccine cold chain. In response to provider requests, TIP has established protocols for the use of mobile immunization clinics in the VFC Program.

The mobile immunization clinic is an extension of the provider's practice and will use the same unique VFC provider identification number (PIN) already assigned to the provider. The mobile immunization clinic must comply with all VFC Program requirements listed in the Provide Agreement. In addition to adhering to all general VFC Program requirements, the following conditions must be met:

1. The provider must be enrolled in the VFC Program in good standing.
2. The VFC provider must have protocols in place to ensure that the outreach efforts meet all VFC requirements, including how the provider is establishing vaccine need (provider profile) and overseeing vaccine ordering for each clinic site to ensure that proper amounts of VFC stock are transported on each clinic day.
3. The mobile immunization clinic must pass storage and handling site-visit; this is an *initial* and *annual* requirement.
 - Any staff participating in the mobile immunization clinics must receive VFC training either by the primary or back-up VFC Coordinator.
 - Any staff participating in the mobile immunization clinics must complete annual VFC training. Training requirement can be met by either participating in the VFC Compliance Site-Visit, completing the two CDC's online "You Call the Shots" modules (Vaccines for Children and Vaccine Storage and Handling) or a face-to-face training with the RIR.
4. Vaccines are required to be shipped to the provider's primary clinic site listed in the Provider Agreement. Vaccines should only be transferred to the mobile unit on the day of the clinic.
5. Mobile Immunization Clinics can only be conducted within the state of Tennessee; VFC-eligible children are not required to be TN residents.
6. The provider must complete the [Mobile Immunization Clinic Log](#) (Appendix) that lists the clinic dates, locations and the vaccine amounts by fund type, VFC and private stock, that will transported for each clinic.
7. Vaccine storage and handling equipment must meet CDC requirements:
 - A stand-alone refrigerator
 - A separate stand-alone freezer
 - DDL with a buffered probe, reporting capabilities, and a current certificate of calibration

- Prior to transferring the vaccine to the mobile immunization clinic the storage units must be operational and temperatures in range (refrigerator temperature steady between 2°-8°C, hovering around 5°C; freezer temperature consistently <-15°C) with a DDL in each storage unit (DDLs stored outside a refrigerator or freezer should be placed in functional storage units at least 6 hours, or the night before, to allow time for them to acclimate)
 - The vaccine should be transferred to the mobile immunization clinic inside a cooler; transfer should not take longer than 15 minutes. If the transfer will take longer than 15 minutes use the Packing Vaccines for Transport during Emergencies guidance or a commercial transport box qualified to maintain proper vaccine temperatures.
8. Only staff that has completed VFC Training can transfer vaccines between provider practice and the mobile unit.
 9. Only amounts of vaccines that are appropriate, based on VFC need, should be transported to each scheduled clinic.
 10. Upon arrival at the clinic site, the mobile clinic staff must ensure that vaccine is stored to maintain appropriate temperature throughout the clinic day:
 - Since the vaccine is at a temporary location, temperature data must be reviewed and documented every hour during the clinic, using a DDL.
 - Temperatures during transport (if >15 minutes) and mobile immunization clinic hours must be documented hourly on the [Hourly Vaccine Temperature Log](#) (Appendix).
 11. At the end of each clinic day, the mobile immunization clinic staff must:
 - Print the temperature data logger report at the end of the clinic day and attach to the mobile clinic temperature log. The primary or back-up VFC Coordinator needs to review temperature logs and sign the Hourly Vaccine Temperature Log prior to the vaccine being returned to the clinic's storage units.
 - Vaccines exposed to TEs must be labeled "Do Not Use", placed in storage unit(s) at proper temperatures, and TIP needs to be contacted promptly per TE procedures described elsewhere in this guide. The TIP Quality Assurance Team will evaluate if the vaccine is still usable.

- Temperature logs from the mobile immunization clinic must be stored with the primary clinic logs and kept on file for 3 years. During a VFC Compliance Site-Visit temperature logs will be reviewed.

12. VFC eligibility must be screened and status documented at the time of service.

- If the eligibility cannot be documented in the EHR, eligibility may be recorded on the [Patient Eligibility Screening Record](#), and scanned into the EHR or maintained in the paper chart.
- All eligibility information must be maintained for **three** years per VFC requirements for maintaining documents.
- The school is responsible to send permission slips/Eligibility Screening Form home with the student prior to the scheduled clinic date, and have available on the date of service.

13. All immunizations must be documented according to the National Childhood Vaccine Injury Act (Statute 42 US Code 300aa-25):

- Name of vaccine
- Date vaccine given
- Name of vaccine manufacturer
- Vaccine lot number
- Signature & title of person administering vaccine
- Address of clinic where given
- Publication date of VIS
- Date VIS given to parent/guardian

14. All immunizations must be entered in TennIIS within seven days of administration.

15. Quality Assurance Visits will be conducted annually for the mobile clinic.

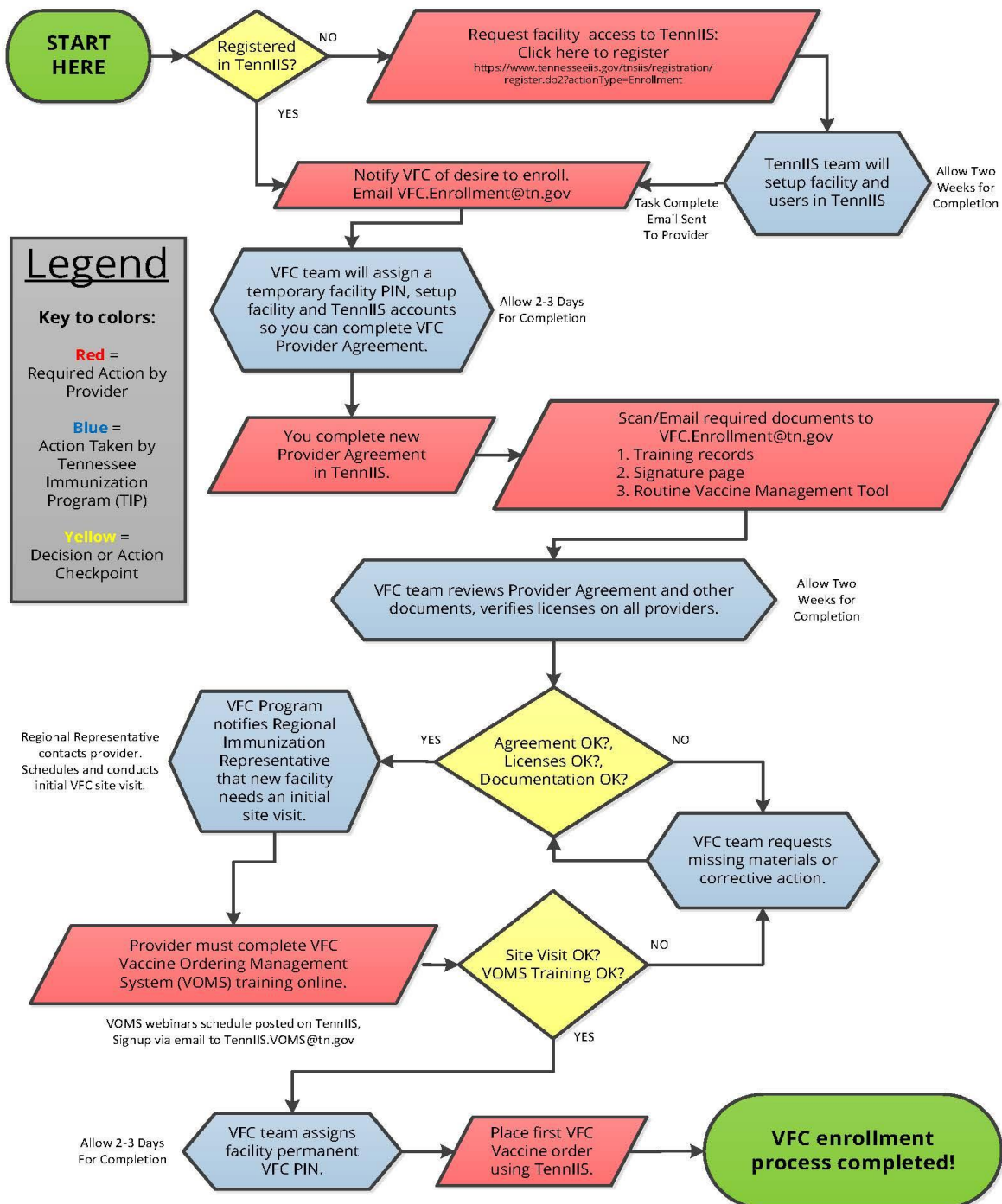
- The mobile immunization clinic will be included in the primary clinic's VFC Compliance Site-Visits. If a compliance visit is not scheduled during the upcoming year, storage and handling visit will be performed.
- Failure to meet the VFC requirements for eligibility, documentation and storage and handling may result in closure of the mobile clinic.

Appendix A: Resources

Resource	Information about Resource
CDC: Epidemiology and Prevention of Vaccine-Preventable Diseases, The Pink Book: Course Textbook	Includes principles of vaccination, immunization general recommendations and strategies, and information regarding vaccine safety, storage and handling, and details regarding administration of individual vaccines. Website: www.cdc.gov/vaccines/pubs/pinkbook/index.html
CDC: Vaccines and Immunizations	Provides information on immunization schedules, publications about vaccine-preventable diseases, and much more. Website: www.cdc.gov/vaccines Phone: 1-800-CDC-SHOT (1-800-232-4636)
CDC: Vaccine Information Statements (VIS) and Email VIS Update Service	Current VIS; sign up to receive update notices via email. Website: www.cdc.gov/vaccines/hcp/vis/index.html
CDC: Vaccine Storage & Handling Toolkit	Information regarding best practices for vaccine storage and handling. Website: http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
Immunization Action Coalition (IAC)	Evidence-based vaccine information, VIS in multiple languages, “Ask the Experts”, free print materials, information on vaccine-preventable diseases, and much more. Website: www.immunize.org

Appendix B

Action Steps to Join the Vaccines For Children (VFC) Program



Appendix C

INSURED EXCEPTIONS

AI/AN with Health Insurance that Covers Immunizations:

AI/AN children are always VFC-eligible. VFC is an entitlement program and participation is not mandatory for an eligible child. For AI/AN children that have full immunization benefits through a primary private insurer, the decision to participate in the VFC program should be made based on what is most cost beneficial to the child and family.

Insured and Medicaid as Secondary Insurance:

Situations occur where children may have private health insurance and Medicaid as secondary insurance. These children will be VFC-eligible as long as they are enrolled in Medicaid. However, the parent is not required to participate in the VFC program. There are options for the parent and provider. These options are described below:

Option 1

A provider can administer VFC vaccine to these children and bill the Medicaid agency for the administration fee.

In most healthcare situations, Medicaid is considered the “payer of last resort.” This means that claims must be filed to and rejected by all other insurers before the Medicaid agency will consider payment for the service. This is not true of the VFC vaccine administration fee for Medicaid-eligible children.

The Medicaid program must pay the VFC administration fee because immunizations are a component of the Medicaid Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program. However, once the claim is submitted to Medicaid, the state Medicaid agency does have the option to seek reimbursement for the administration fee from the primary insurer.

Please note: If the state Medicaid agency rejects a claim for a vaccine administration fee for a child with Medicaid as secondary insurance, stating the claim must first be submitted to the primary insurer for payment, the provider should notify the awardee. The awardee should notify their CDC project officer so that CDC can work with CMS to educate the state Medicaid agency and correct the situation.

Considerations regarding this option:

- This is the easiest way for a provider to use VFC vaccine and bill Medicaid for the administration fee.
- There are no out-of-pocket costs to the parent or guardian for the vaccine or the administration fee.

Option 2

A provider can administer private stock vaccine and bill the primary insurance carrier for both the cost of the vaccine and the administration fee.

- If the primary insurer pays less than the Medicaid amount for the vaccine administration fee, the provider can bill Medicaid for the balance of the vaccine administration fee, up to the amount Medicaid pays for the administration fee.
- If the primary insurer denies payment of vaccine and the administration fee, the provider may replace the privately purchased vaccine with VFC vaccine and bill Medicaid for the administration fee. The provider must document this replacement on the VFC borrowing form.

Considerations regarding this option:

- The provider may be reimbursed a higher amount if privately purchased vaccine is administered and both the vaccine and the administration fee are billed to the primary insurer.
- The provider should choose from the vaccine inventory that is most cost-effective for the family.
- The parent/guardian of a child with Medicaid as secondary insurance should never be billed for a vaccine or an administration fee.

Reference: Centers for Disease Control and Prevention. Vaccines for Children Program Operations Guide, 2016 Edition.

Appendix D

Vaccines for Children (VFC) Program Patient Eligibility Screening Record

A record of all children 18 years of age or younger who receive immunizations must be kept in the health care provider's office for 3 years or longer depending on state law. The record may be completed by the parent, guardian, individual of record, or by the health care provider. VFC eligibility screening and documentation of eligibility status must take place with each immunization visit to ensure the child's eligibility status has not changed. While verification of responses is not required, it is necessary to retain this or a similar record for each child receiving vaccine. Providers using a similar form (paper-based or electronic) must capture all reporting elements included in this form.

1. Child's Name : _____
Last Name First Name MI
2. Child's Date of Birth: ____/____/____
3. Parent/Guardian/Individual of Record: _____
Last Name First Name MI
4. Primary Provider's Name: _____
Last Name First Name MI
5. To determine if a child (0 through 18 years of age) is eligible to receive federal vaccine through the VFC and state programs, at each immunization encounter/visit enter the date and mark the appropriate eligibility category. *If Column A-D is marked, the child is eligible for the VFC program. If column E, F or G is marked the child is not eligible for federal VFC vaccine.*

	Eligible for VFC Vaccine				Not eligible for VFC Vaccine		
	A	B	C	D	E	F	G
Date	Medicaid Enrolled	No Health Insurance	American Indian or Alaskan Native	*Underinsured served by FQHC, RHC or deputized provider	Has health insurance that covers vaccines	**Other underinsured	***Enrolled in CHIP (CoverTN)

*Underinsured includes children with health insurance that does not include vaccines or only covers specific vaccine types. Children are only eligible for vaccines that are not covered by insurance. In addition, to receive VFC vaccine, underinsured children must be vaccinated through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) or under an approved deputized provider. The deputized provider must have a written agreement with an FQHC/RHC and the state/local/territorial immunization program in order to vaccinate underinsured children.

** Other underinsured are children that are underinsured but are not eligible to receive federal vaccine through the VFC program because the provider or facility is not a FQHC/RHC or a deputized provider. However, these children may be served if vaccines are provided by the state program to cover these non-VFC eligible children.

***Children enrolled in separate state Children's Health Insurance Program (CHIP). These children are considered insured and are not eligible for vaccines through the VFC program. Each state provides specific guidance on how CHIP vaccine is purchased and administered through participating providers.

CDC FORM-2014

Please Note: In Tennessee the Local Health Departments are the only deputized providers. CDC form is available at:

http://www.tn.gov/assets/entities/health/attachments/Patient_Eligibility_Screening_Record.pdf

Reference: Centers for Disease Control and Prevention. Vaccines for Children Program Operations Guide, 2016 Edition.

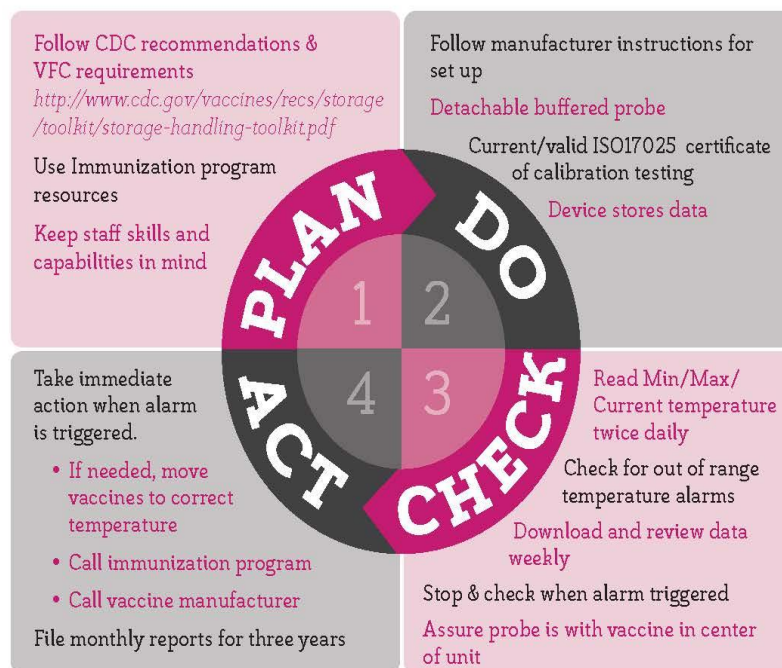
Appendix E



For more information
go to
immunizationmanagers.org/VSH

Educational resource
created with support from
Berlinger USA

A STEP-BY-STEP GUIDE TO SELECTING AND USING A DATA LOGGER FOR VACCINE INVENTORY



USING A DATA LOGGER – THE DETAILS

PLAN 1

- Detachable temperature probe in buffered material (e.g. bio-safe glycol)
- Check for availability of training tools to support providers and staff before purchasing
- ISO 17025 calibration certificate
- Continuous temperature recording: Minimum every 15 minutes
- Memory: Minimum 4,000 readings or 39 days
- Operating range: -25°C to +55°C (-13°F to +133°F)
- Uncertainty/Accuracy: $\pm 0.5^\circ\text{C}$
- Resolution: 0.1°C (or 1 decimal point)
- Battery life: Minimum 6 months
- Track when temperatures are checked: Minimum 2x/day
- LCD display with: current, Min and Max temperatures visible – PLUS alarm status OK or Not OK
- Report: Shows alarms, temperature ranges and duration of excursions
- Assess custom software to avoid installation issues – especially with hospitals and clinics
- Data export capability: Excel, CSV, Txt

DO 2

- Place probe in the middle of the unit with vaccines.
- Thread probe wire through door hinge and tape in place (inside & outside the unit).
- First week: reveals storage equipment temperature issues right away
- Know where to find the ISO certificate – Check for an expiry date on the data logger
- Both audible and visual alarms are preferred

CHECK 3

- Read and record temperatures 2x daily noting data/time/temp/initials
 - Note: Initials may be in a separate log book
 - Some data loggers offer this feature
- Download and review reports weekly
 - PDF reports simplify record keeping

ACT 4

- Take immediate action: when there is an alarm
 - Move vaccines to a storage unit operating at the correct temperatures
 - Print report and look for clues to the problem
 - o Eg. Is the ave. temperature 5.0°C (41°F)?
 - o If not it is too cold or too warm in the unit
 - Send alarm information to immunization program and vaccine manufacturer
 - Alarm reports require the duration of the alarm period and the highest or lowest temp. during the alarm
- Store monthly reports per state/VFC requirements

Display screen

Thread flat wire through gasket on hinged side of unit

Stabilize vial with probe on shelf

Duct tape wire to wall

For more information go to:
immunizationmanagers.org/VSH

Educational resource created with support from Berlinger USA

Can be found on the Association of Immunization Managers website:

<http://www.immunizationmanagers.org/page/vsh> (last accessed 9/27/2016)

Appendix F

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately, and if you can do so safely, follow the emergency packing procedures for refrigerated vaccines.

1 Gather the Supplies



Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.



Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.



Insulating material — You will need two of each layer

- **Insulating cushioning material** – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.



Temperature monitoring device – Digital data logger (DDL) with buffered probe. Accuracy of $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**



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Visit www.cdc.gov/vaccines/SandH
for more information, or your state
health department.

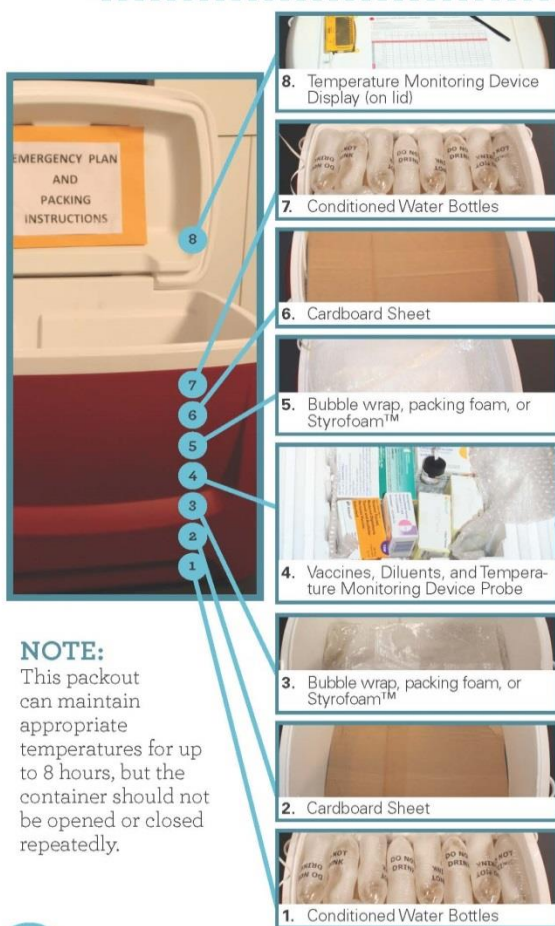
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Packing Vaccines for Transport during Emergencies

2 Pack for Transport

Conditioning frozen water bottles

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice “sticks,” put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.



NOTE:
This packout can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.

Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.

Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.

Insulating material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™

Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe.

Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.

Vaccines – Stack boxes of vaccines and diluents on top of insulating material.

Insulating material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).

Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

3 Arrive at Destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.

Storage – Transfer boxes of vaccines quickly to storage refrigerator.

Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines “Do Not Use” and store at appropriate temperatures until a determination can be made.

Can be found on the CDC's website at:

<http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf> (last accessed 9/27/2016)